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Preventing Overdiagnosis of Implantable Cardioverter-Defibrillator Lead Fractures Using Device Diagnostics

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Objectives This study sought to use implantable cardioverter-defibrillator (ICD) diagnostics to discriminate ICD lead fractures from normally functioning leads with high impedance and from connection problems between the lead and header.

Background ICD diagnostics facilitate identification of fractures, but there are no accepted criteria for discriminating fractures from other causes of high impedance and/or nonphysiological "noise" oversensing.

Methods We analyzed a development set of 91 leads to construct a stepwise algorithm based on ICD diagnostics. It included 40 fractures, 30 connection problems, and 21 functioning leads that triggered high-impedance alerts. Then we applied this algorithm to an independent test set of 100 leads: 70 fractures and 30 intact leads with connection problems that were misdiagnosed clinically as fractures. In the algorithm, either extremely high maximum impedance or noise oversensing with a normal impedance trend indicated a fracture. A short interval from surgery to impedance rise or prolonged stable impedance after an abrupt rise indicated a connection problem. A gradual impedance increase or stable, high impedance indicated a functioning lead.

Results In the test set, the algorithm correctly classified 100% of fractures (95% confidence interval [CI]: 95% to 100%) and 87% of connection problems that were misdiagnosed as fractures (95% CI: 70% to 95%).

Conclusions An algorithm using only ICD diagnostics identifies leads with oversensing or high impedance as fractures or connection problems with a high degree of accuracy. (J Am Coll Cardiol 2011;57:2330–9) © 2011 by the American College of Cardiology Foundation

Pace-sense fractures of implantable cardioverter defibrillator (ICD) leads are diagnosed by oversensing of characteristic, nonphysiological signals ("noise") and/or an increase in pacing impedance (1–4). Rapid diagnosis is important because the time between abnormal diagnostics and 1 or multiple inappropriate shocks caused by rapid oversensing may be short (1,3,4). However, lead replacement is associated with significant morbidity and rare deaths (5), and an incorrect diagnosis may result in replacement of normally functioning leads (6).

Our goal is to reduce overdiagnosis of lead fractures. Previously, we reported characteristics of noise that discriminate fractures from other causes of rapid oversensing with normal impedance (7,8). The differential diagnosis of high impedance and noise oversensing includes connection problems between the lead and ICD (9,10); the differential diagnosis of high impedance also includes normally functioning leads. Neither requires lead replacement. In the present study, we analyzed characteristics of impedance trends and the relationship between these characteristics and noise oversensing. We hypothesized that these ICD diagnostics can be used to construct a comprehensive algorithm that discriminates lead fractures from normally functioning leads with high impedance and connection problems, including those that were misdiagnosed as fractures.

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Methods

We analyzed diagnostics from ICD "save-to-disk" or remote-monitoring data files. First, we performed an exploratory analysis in a development set to identify discriminating criteria. We used these criteria to construct a stepwise algorithm. Then we applied this algorithm to an independent test set.

Abbreviations and Acronyms

CI = confidence interval

ICD = implantable cardioverter-defibrillator

LIA = lead integrity alert

RPA = returned product analysis

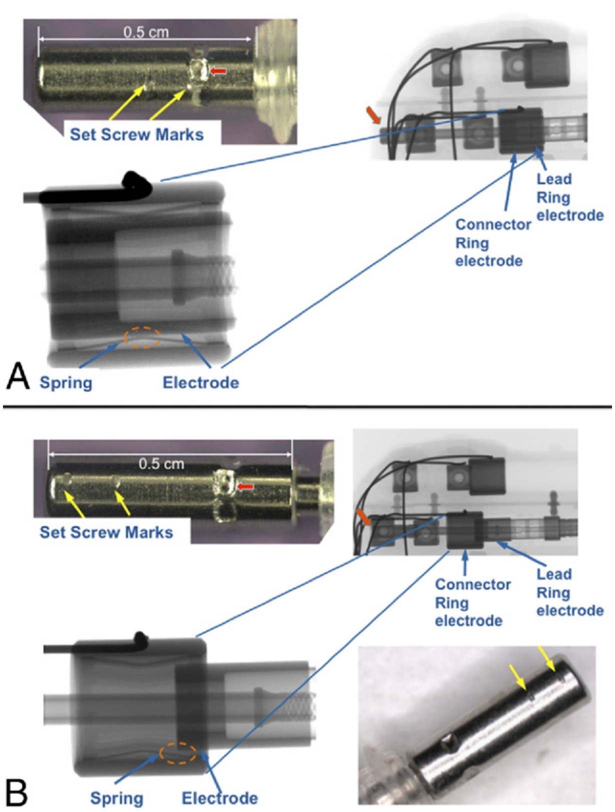

Figure 1 **RPA Diagnosis of Connection Problems**

Complete **(A)** and incomplete **(B)** insertion of lead pace-sense pin into header. Each panel shows 3 images related to a demonstration lead and header connected on a laboratory bench: photograph of lead pin at **top left** and analytical quality x-rays at **top right** and **bottom left.** Additionally, **B** shows a photograph of a representative lead in the present study **(lower right).** In each panel, the x-ray at **top right** shows lead inserted into header, corresponding to a high-quality clinical image. **Red arrow** denotes end of lead pin. Enlarged x-ray at **bottom left** shows the ring electrode of the lead **(right arrow)** and its corresponding connector ring on the header. Lead ring electrode and connector ring electrode are designed to contact via a conducting spring that ensures electrical conduction **(left arrow). Dashed orange circle** denotes site of electrical connection. Photograph at **top left** shows pair of marks where set screws indent the lead **(yellow arrows).** Larger marks **(horizontal red arrow)** are caused by the tool used to crimp the lead pin to the conductor assembly during construction and are expected. **(A) Top right** panel shows the tip of the lead pin fully inserted, extending to left past the connector post. Enlarged x-ray shows lead-ring electrode aligned with spring of connector-ring. Photograph shows set-screw marks in correct location (≥0.330 cm from lead tip). **(B) Lower left** panel shows the tip of the lead pin inserted incompletely, flush with the connector post. Enlarged x-ray shows lead-ring electrode barely touching spring of connector ring. **Lower left** photograph shows set screw marks in incorrect location (<0.165 cm from the lead tip). **Lower right** photograph shows set screw marks on a lead in the present study classified by returned product analysis (RPA) as a connection problem. This lead presented as an abrupt impedance rise with no oversensing 57 months after implantation. Set screw marks are in incorrect location, similar to photograph at **top left.**

Patient groups: development and test sets. The "development set" of leads from 91 patients consisted of 30 leads with connection problems, 40 Fidelis fractures, and 21 functioning Fidelis leads with high impedance. The "test set" of leads from 100 patients included 30 connection problems and 70 fractures; fractures were divided prospectively into a subgroup of 40 consecutive Fidelis leads and a subgroup of 30 consecutive non-Fidelis, multilumen (Sprint-Fidelis family, Medtronic, Inc., Minneapolis, Minnesota) leads.

We included functioning leads in the development set with the goal of identifying unique features of presumed electrode-myocardial interface problems. Because these leads remained implanted, we could not determine the cause of their high impedance definitively. Thus, we did not include them in the test set.

Reference standards for lead status. This study used both clinical criteria and criteria based on returned product analysis (RPA) of explanted leads. Fractures were determined only by RPA. Normally functioning leads with high impedance were defined by the absence of clinical problems during follow-up. In the test set, connection problems were determined only by RPA. In the development set, they were determined either clinically or by RPA.

RPA REFERENCE STANDARDS. Lead fracture was determined if analysis of an explanted lead or lead fragment identified a fracture. In contrast, a lead was considered intact (not fractured) only if it was returned in its entirety for analysis; no abnormality was identified by visual inspection and low-power (10× to 30×) light microscopy except for minor, typical extraction-related changes; and unipolar electrical continuity measurements were within impedance specifications for each conductor, both at rest and under various positions of mechanical stress. Impedance specifications varied depending on lead model and length (e.g., 21.6 ± 3.6 Ω for the tip electrode and <47 Ω for the ring electrode of a 65-cm, model 6949 Fidelis lead).

If the lead pin is not inserted completely into the header, the ring electrode contacts its corresponding conductor incompletely or intermittently, resulting in a connection problem. Tightened set screws result in identifiable marks on the pin. We used this observation to determine incomplete insertion of the pin into the ICD header. When leads were explanted for clinical misdiagnosis of pace-sense fracture and RPA determined they were intact, the lead pin was inspected under low-power microscopy. A connection problem was diagnosed if the set-screw mark was within 0.165 cm from the tip of the pin (normal distance ≥0.330 cm) (Fig. 1).

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CLINICAL DETERMINATION. Clinical determinations were applied to leads in the development set that were not explanted. Connection problems met 3 criteria: 1) incomplete lead-pin insertion into the generator's header was identified at a subsequent surgical procedure; 2) complete insertion of the pin corrected the clinical problem (high impedance and/or oversensing); and 3) neither the generator nor the lead was replaced.

Leads with high and rising impedance that triggered the high-impedance feature of the lead integrity alert (LIA) (3) were determined to be "functioning" normally if they had no evidence of lead or ICD system malfunction—including any abnormality of pacing, sensing, or high voltage conductors—during minimum follow-up of 1 year after the impedance alert (median: 20 months, range 13 to 36 months). These leads did not undergo RPA because they remained implanted. This functional determination differs qualitatively from a RPA reference standard. We assumed that determination of a functioning lead excluded a clinically significant fracture, but not a connection problem.

Study inclusion criteria. Leads were included only if a save-to-disk or remote-monitoring file had adequate data preceding the patient's clinical presentation. Fractures were consecutive leads identified from the Medtronic RPA database that were explanted because a physician diagnosed pace-sense fracture. Separate database queries were performed for Fidelis and non-Fidelis leads. Leads with connection problems determined by RPA were consecutive leads identified from the RPA database that met study criteria and were extracted because a pace-sense lead fracture was *misdiagnosed* by a physician due to high impedance or noise (7,8) oversensing (Figs. 2A and 2B). We did not analyze leads with connection problems that were explanted for reasons other than misdiagnosis of fracture. Clinically

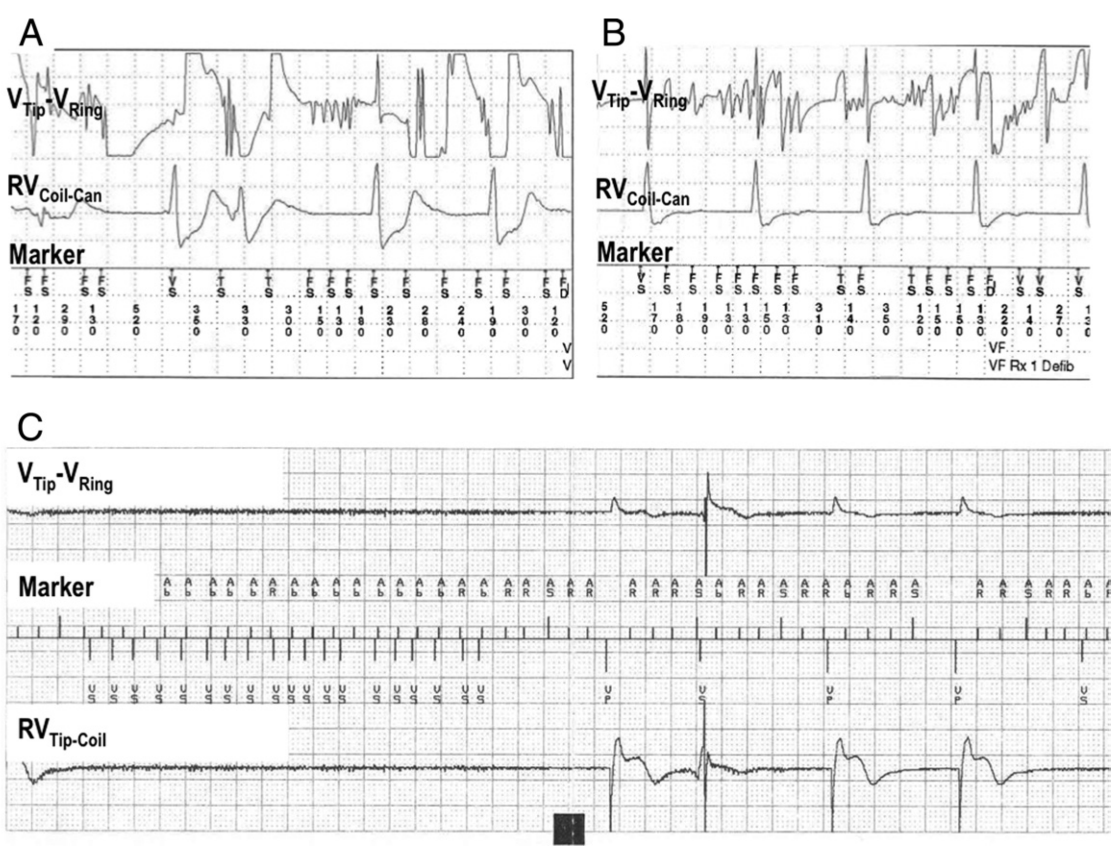

Figure 2 **Examples of Oversensing**

(A) Fidelis lead fracture. **(B)** Connection problem. **(C)** Diaphragmatic myopotentials. Panels **A** and **B** show electrograms from save-to-disk files for leads in the present study. Each shows pace-sense (V_{Tip}-V_{Ring}) and high-voltage ($RV_{Coil\text{-}Can}$) electrograms with ventricular marker channel. Noise is limited to the pace-sense electrogram. Noise signals have high-frequency and highly variable amplitude; they occur intermittently, separated by periods of isoelectric baseline. Noise characteristics do not distinguish fractures from connection problems. **C** shows a real-time recording from an intact lead with normal connection markings that was explanted because it was misdiagnosed as a fracture. It was not included in the present study. This panel displays pace-sense and integrated bipolar ($RV_{Tip\text{-}Coil}$) electrograms at the same gain, as well as atrial and ventricular marker channels. The extremely high-frequency oversensed signal (seen best in **left half** of tracing) has a low, approximately constant amplitude, appearing almost as a thickening of the baseline. It varies with respiration, but not as rapidly as lead- or connection-related oversensing. It inhibits ventricular pacing in this pacemaker-dependent patient. Rapid markers on the atrial marker channel result from sensed atrial fibrillation. AS, AB, and AR = atrial intervals in the sensing, blanking, and refractory periods; FD = fibrillation detection; VP = ventricular pacing; VS, TS, and FS = ventricular intervals in the "sinus," tachycardia, and fibrillation rate zones.

determined functioning leads included all functioning Fidelis leads that triggered the LIA's impedance alert in a previous report (3). Clinically determined connection problems included all surgically corrected connection problems that triggered the LIA's impedance alert in the same report.

Impedance measurements. The Medtronic ICDs in this study measure lead impedance once daily within the range 0 to 16,382 Ω, although the programmer and remote-monitoring software truncate the maximum displayed value at 2,500 Ω. The impedance trend stores up to the last 14 daily measurements and up to 80 weekly minimum and maximum values. For impedance monitoring, the threshold for an impedance alert is programmable between 1,000 and 2,500 Ω. For LIA, the threshold is based on the average of the most recent measurements (3).

Impedance values were extracted from impedance trends and analyzed using Matlab (version 7.7, Matlab, Natick, Massachusetts). For leads subjected to RPA, we analyzed trends up to the date of explantation. For functioning leads, we analyzed trends up to the first interrogation after the impedance alert.

Algorithm development. We selected variables related to impedance trends and oversensing. Using the development set, we identified discriminatory thresholds for each variable. Then, we evaluated various combinations of criteria to construct an algorithm.

Variables were selected based on clinical conjectures. Five variables were related to the shape of impedance trends, and 2 were related to their time course. Changes at the electrode-myocardial interface typically cause gradual rises to stable, high impedances, but high impedances in fractures and connection problems are abrupt and intermittent. Thus, we analyzed: 1) abrupt versus gradual impedance rise; and 2) stable high impedance. Open circuits resulting in very high impedance occur with fractures but not connection problems; thus we analyzed: 3) maximum impedance. Incomplete insertion of the lead pin into the connector may result in long intervals of baseline impedance after an abrupt rise, but fractures do not show a consistent return to baseline impedance. Thus, we analyzed: 4) longest return to baseline after an abrupt rise. Connection problems typically have at least 1 high impedance measurement over weeks to months. Conversely, 5) characteristic, nonphysiological noise oversensing (7,8) without an impedance rise indicates a fracture. Connection problems are often identified perioperatively, whereas fractures develop late after lead implant. Thus, we analyzed: 6) time from last ICD surgical procedure to first oversensing or abrupt impedance rise, and 7) time from lead implant to first abrupt impedance rise.

Based on analysis of the development set, we used these definitions related to impedance trends: "Initial impedance" was the first, saved minimum value. An "impedance rise" was defined as any (daily or weekly) measurement that exceeded the *initial* impedance by 350 Ω or 60%. "Baseline impedance" was defined as the median of weekly minimum values for the 3 previous weeks, updated weekly until an abrupt impedance rise occurred. Thereafter, it remained constant at its last value. An "abrupt impedance rise" was any impedance measurement that exceeded the *current, moving baseline* by 350 Ω or 60% (Figs. 3A, 3B, and 3D). An impedance rise that did not qualify as abrupt was defined as "gradual" (Fig. 3C). "Return to baseline" impedance after an abrupt rise was defined as a daily impedance measurement that returned to within 350 Ω and 60% of baseline impedance after an abrupt rise (Fig. 3A). An abrupt impedance rise was considered *stable* if the maximum value did not return to baseline for the 2 weeks after the rise and the minimum value exceeded 65% of the maximum throughout (Fig. 3D).

Statistical analysis. The study's prospectively defined endpoints were based on the algorithm's performance on the test set: the fractions of correctly classified fractures and connection problems. Data are presented as mean ± SD. Ninety-five percent confidence intervals (CIs) were calculated using the binomial distribution. Non-normal, continuous variables were compared using the Wilcoxon rank-sum test. Reported p values have not been adjusted for multiple comparisons and are not study endpoints. A p value <0.05 was considered significant for single comparisons.

Results

Stepwise algorithm. The Online Appendix provides data for individual leads in the development set. Figure 4 shows the algorithm developed from these data. A lead is classified as having a connection problem if it fulfills 1 of 3 criteria: 1) either noise oversensing or an impedance rise occurs in the first 30 post-operative days after lead implantation or generator change (Step 1); 2) an abrupt impedance rise is followed by a return to baseline longer than 45 days (Step 5); or 3) an abrupt impedance rise occurs within 200 days of lead implantation (Step 6). A lead is classified as a fracture if it fulfills 1of 2 criteria: 1) noise oversensing occurs without an impedance rise (Step 3B); or 2) an abrupt impedance rise exceeds 10,000 Ω (Step 4). In addition, a lead with an abrupt impedance rise is classified as a fracture if it is not given another classification (Step 6). A lead is classified as functioning if it fulfills both of 2 criteria: 1) noise oversensing does not occur; and 2) either the impedance rise is gradual or high impedance is stable after an abrupt rise. Figure 5 shows a conceptual view of the algorithm.

The development set. FUNCTIONING-LEAD GROUP. Two features discriminated functioning leads with high impedance from fractures and connection problems. First, gradual impedance rises or stable high impedance after an abrupt rise occurred in 9 of 21 functioning leads (43%, 95% CI: 24% to 63%) versus 0 of 70 fractures and connection problems (0%, 95% CI: 0% to 5%, $p < 0.0001$). Second, maximum impedance >2,500 Ω did not occur in any of 21 functioning leads (0%, 95% CI: 0% to 15%) versus 41 of 70 fractures or connection problems (59%, 95% CI: 47% to 69%, $p < 0.0001$).

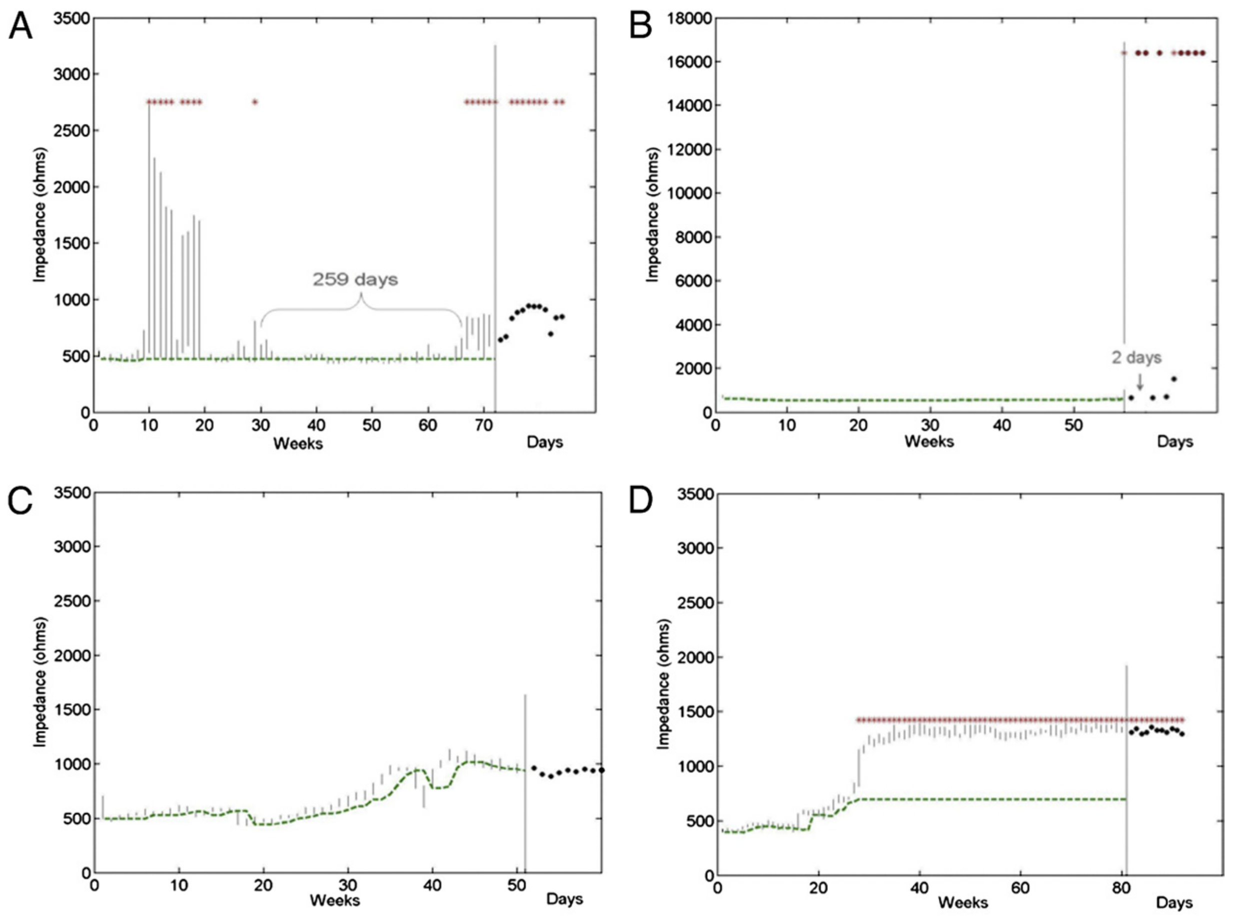

Figure 3 **Impedance Trends for Individual Patients Classified Correctly by Algorithm**

To the **left** of the **longest vertical line,** data are displayed as **vertical lines** connecting weekly maximum and minimum values. To **right, black points** indicate daily values. **Dotted green line** denotes baseline impedance calculated for weekly values. **Red stars** denote impedance measurements that fulfill criteria for an abrupt rise. **(A)** Connection problem with first abrupt rise occurring 10 weeks post-implantation with long return to baseline (259 days). **(B)** Fracture with abrupt impedance rise to open circuit. Longest return to baseline is 2 days. **(C)** Gradual impedance rise in functioning lead. **(D)** Abrupt rise to high, stable impedance in functioning lead.

ALGORITHM PERFORMANCE. The algorithm correctly classified 40 of 40 fractures (100%, 95% CI: 91% to 100%) and 28 of 30 connection problems (93%, 95% CI: 79% to 98%). Of the 21 functioning leads, the algorithm classified 11 as connection problems (52%), 9 as functioning (43%), and 1 as a fracture (5%). Including functioning leads and connection problems, overall accuracy for rejection of lead fracture was 48 of 51 (94%, 95% CI: 84% to 98%). Development set results represent "best case" performance.

Test set. Table 1 summarizes clinical presentations. Inappropriate shocks were more common in fractures than connection problems were (51 of 70, 73% vs. 7 of 30, 23%; $p < 0.0001$). Table 2 shows the number of patients in each group whose values exceeded thresholds for each variable established from the development set. Figure 6 provides individual patient data.

IMPEDANCE TRENDS. An impedance rise occurred in 43 of 70 fractures (61%, 95% CI: 50% to 72%) and 28 of 30 connection problems (93%, 95% CI: 79% to 98%). All impedance rises were abrupt and all but 1 were stable. The stable rise corresponded to a connection problem.

Figure 6A shows that impedances greater than the threshold 10,000 Ω occurred only in fractures: 15 of 70 fractures (21%, 95% CI: 17% to 40%) versus 0 of 30 connection problems (0%, 95% CI: 0% to 11%, $p = 0.0119$). Figure 6B plots individual values for the duration of return to baseline after an abrupt rise. Return longer than the threshold of 45 days occurred in 0 of 70 fractures (0%, 95% CI: 0% to 5%) versus 13 of 30 connection problems (43%, 95% CI: 27% to 60%, $p < 0.0001$).

OVERSENSING. For leads presenting after post-operative day 30, noise oversensing without an impedance rise occurred in 0 of 25 connection problems (0%, 95% CI: 0% to 13%) versus 27 of 70 fractures (39%, 95% CI: 28% to 50%; $p = 0.0006$). In these 27 fractures, the median value of maximum impedance was 528 Ω (range 443 to

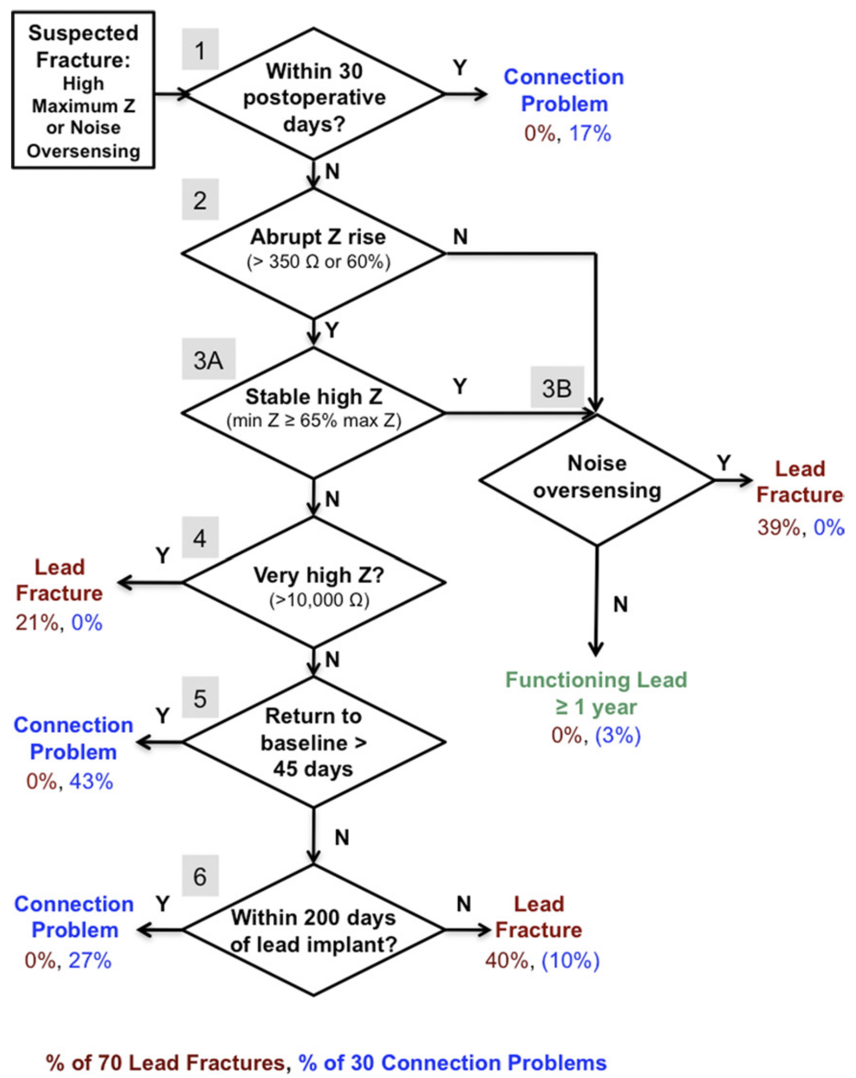

Figure 4 **Algorithm for Discrimination of Pace-Sense Lead Fractures From Connection Problems and Functioning Leads With Impedance Rises**

See text for details. Numbers in **gray boxes** denote algorithm steps. Percentages at each step indicate algorithm's classification for 70 fractures **(maroon text)** and 30 connection problems **(blue text)** in the test set. Values in **parentheses** denote incorrect classification.

1,224 Ω). Oversensing without an impedance rise was more common in non-Fidelis fractures (21 of 30, 70%) than in Fidelis fractures (6 of 40, 15%, $p < 0.0001$). Two connection problems presented with oversensing but no impedance rises, on post-operative days 1 and 14, respectively.

TIME FROM SURGERY TO FIRST IMPEDANCE RISE. Figure 6C plots the interval from the last procedure to the first impedance rise for individual patients with impedance rises. Considering all connection problems with impedance rises ($n = 28$), the first rise occurred within 30 days of the last surgery in only 3 leads (11%), within the first 90 days in 9 leads (32%), from 91 to 180 days in 5 leads (18%), and after 180 days in 13 leads (46%). The last surgery was the ICD system implantation in 98 patients (98%) and generator change in 2 patients (2%).

ALGORITHM PERFORMANCE. In Figure 4, percentages of leads classified correctly and incorrectly (in parentheses) are shown at each step. The algorithm correctly classified 70 of 70 fractures (sensitivity: 100%, 95% CI: 95% to 100%) and 26 of 30 connection problems (specificity: 87%, 95% CI: 70% to 95%). Rates of correct classification were similar in the development and test sets for both fractures (100% vs. 100%) and connection problems (93% vs. 87%, $p = 0.6707$). In the test set, the positive predictive value for fracture was 70 of 74 (95%, 95% CI: 87% to 98%); the negative predictive value was 26 of 26 (100%, 95% CI: 87% to 100%).

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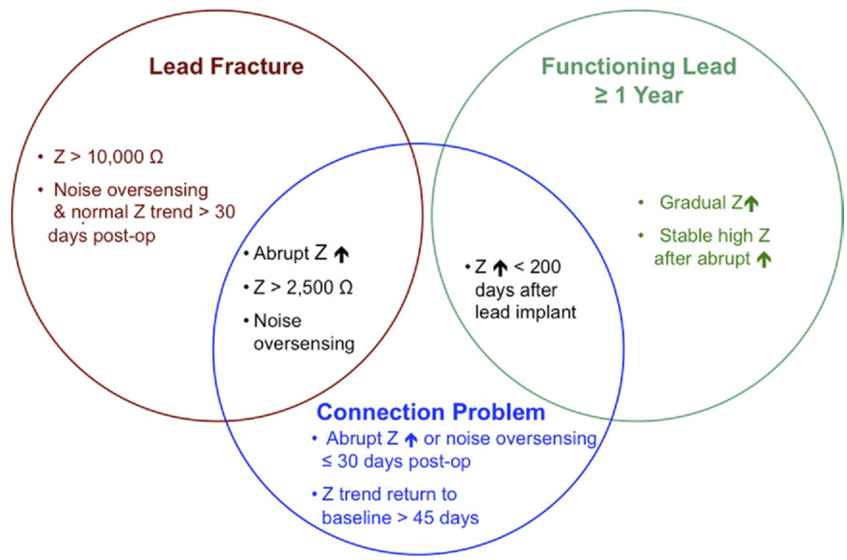

Figure 5 **Venn Diagram of Diagnostic Features Used by Algorithm**

The algorithm uses those features in only 1 circle as a diagnostic of the corresponding condition. Features in overlapping circles may occur in more than 1 condition. See text for details. post-op = post-operative.

Misclassified leads. Figure 7A shows the impedance trend for a typical case classified as a connection problem. There is an early abrupt rise, a highly erratic impedance trend, and a long return to baseline. Figures 7B and 7C show impedance trends of the functioning lead that was misclassified as a fracture. Figure 7B shows a late, gradual rise interrupted by an abrupt increase, truncated by the end of data collection 20 days later. The lead was misclassified based on the late abrupt rise. Figure 7C, from a subsequent interrogation, shows a long return to baseline (504 days) that would have been classified as a connection problem. It was not included because we analyzed leads at time of the first data file that showed an impedance rise, resulting in worst-case for misdiagnosis.

All 5 misclassifications of connection problems as fractures occurred because "fracture" is the default classification when the first impedance rise occurs more than 200 days after implant. Both leads in the development set and 2 of 3 in the test set had similar trends: They were extracted shortly after the impedance rise, preventing subsequent evaluation for stable impedance. The remaining lead had highly variable impedances for 210 days between the impedance rise and extraction.

Figure 7D shows the connection problem that was classified as a functioning lead. Oversensing did not occur. There is an abrupt increase during a more gradual impedance rise. The impedance rise is classified as stable because the minimum impedance exceeds 65% of the maximum throughout.

Table 1 **Clinical Presentations of Patients in the Test Set**

	Fracture		
	Fidelis (n = 40)	Non-Fidelis (n = 30)	Connector (n = 30)
Impedance alert only	7 (18%)	0 (0%)	8 (27%)
Noise oversensing only*	9 (23%)	26 (87%)	2 (6%)
Impedance alert and noise oversensing*	24 (60%)	4 (13%)	12 (40%)
High and increasing impedance without alert	0 (0%)	0 (0%)	8 (27%)

Data presented as n (%). Fidelis is a product of Medtronic, Inc. (Minneapolis, Minnesota).
*Oversensing is defined as nonphysiological noise oversensing confirmed by stored electrograms.

Table 2 **Number and Percentage of Patients in the Test Set in Relation to Threshold Values From the Development Set**

	Fracture		
	Fidelis (n = 40)	Non-Fidelis (n = 30)	Connector (n = 30)
Gradual impedance rise	0 (0%)	0 (0%)	0 (0%)
Stable, high impedance	0 (0%)	0 (0%)	1 (3%)
Maximum impedance			
>2,500 Ω	20 (50%)	4 (13%)	11 (37%)
≥10,000 Ω	13 (33%)	2 (7%)	0 (0%)
Return to baseline >45 days after impedance rise	0 (0%)	0 (0%)	13 (43%)
Time to oversensing or impedance rise (days)			
≤30 days after implant or generator change	0 (0%)	0 (0%)	5 (17%)
≤200 days after lead implant	0 (0%)	0 (0%)	16 (53%)
Noise oversensing with normal impedance after post-operative day 30	6 (15%)	21 (70%)	0 (0%)

Data presented as n (%). Fidelis is a product of Medtronic, Inc. (Minneapolis, Minnesota).

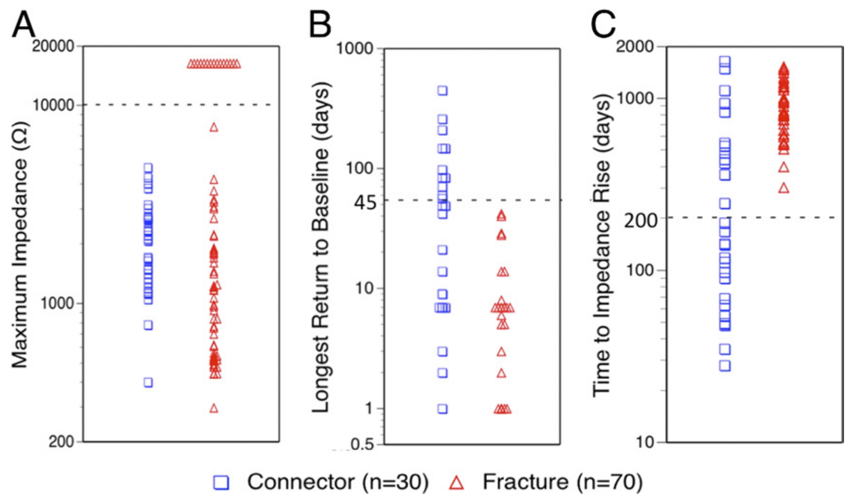

Figure 6 **Individual-Patient Data From Impedance Trends in Test Set**

Connector problems are plotted in **blue** and fractures in **red. Horizontal dotted line** denotes threshold used in algorithm based on the development set. **(A)** Maximum impedance. **(B)** Longest return to baseline after abrupt impedance rise. **(C)** Time from last surgery to first abrupt rise. **A** includes points for all 100 test set patients. **B and C** include points for the 71 patients with impedance rises.

Discussion

Early diagnosis of ICD lead fractures is important to reduce morbidity from loss of pacing, inappropriate ICD shocks, and/or ineffective treatment of ventricular tachyarrhythmias (1–4); however, overdiagnosis may result in unnecessary lead replacement risking morbidity and rare deaths (5). ICD diagnostics facilitate identification of fractures (1–4,11), but individual diagnostics are nonspecific (3,8,11). Furthermore, there are no evidence-based criteria for discriminating fractures from other causes of high impedance and/or noise oversensing. The principal finding of our study is that diagnostic accuracy can be improved by combining multiple characteristics of impedance trends and the relationship between these characteristics and noise oversensing. This approach can discriminate fractures from connection problems that were misdiagnosed as fractures.

Discriminating fractures from connection problems. Connection problems include loose set screws (9), air trapped in the header escaping through seal plugs (12,13), weakened ICD header bonds (14), adapter problems (15), and incomplete contact between the lead pin and header (10). The literature is limited to reports of a few or single cases, which presented intraoperatively or perioperatively.

In the present study, most connection problems that were misdiagnosed as fractures presented after the perioperative period; 46% presented more than 6 months later. The Online Appendix shows that connection problems that were diagnosed correctly after LIA alerts also presented primarily after the perioperative period. Thus, connection problems are an important cause of late impedance rises. However, fractures did not occur early after implantation. The earliest presented at 256 days.

Our data support 3 criteria related to impedance trends for discriminating fractures from connection problems. First, very high impedance, indicating an open or nearly open circuit, is specific for fracture. Second, a long return to baseline after an abrupt rise occurs only in connection problems. It may occur if stress occasionally alters a mostly adequate connection with incomplete insertion of the pin. This criterion is helpful when the first impedance rise occurs late after surgery or an early rise is insufficient to trigger an impedance alert, but not at the first impedance rise. Third, fractures may result in oversensing without abnormal impedance, but connection problems do not if multiple measurements are made over time. Such fractures may represent breaks involving 1 or a few filars of the multifilar cable conductor to the ring electrode (16); the fractured filars may generate noise signals while the remaining filars conduct sufficiently to prevent an impedance increase at the measured resolution.

Discriminating fractures from functioning leads. Gradual, stable impedance rises in normally functioning leads are presumed to occur at the electrode-myocardial interface. We are unaware of any report that characterizes impedance rises at the electrode-myocardial interface for ICD leads or of evidence-based criteria for discriminating such changes from fractures and connection problems. For example, Kallinen et al. (4) reported 3 patients with normally functioning Fidelis leads who had gradual impedance increases. The leads were replaced because of concern that they might be fractured. By definition, functioning leads do not have noise oversensing.

Our algorithm assumes that noise oversensing is identified accurately (3,8). In reviewing explanted leads, we found

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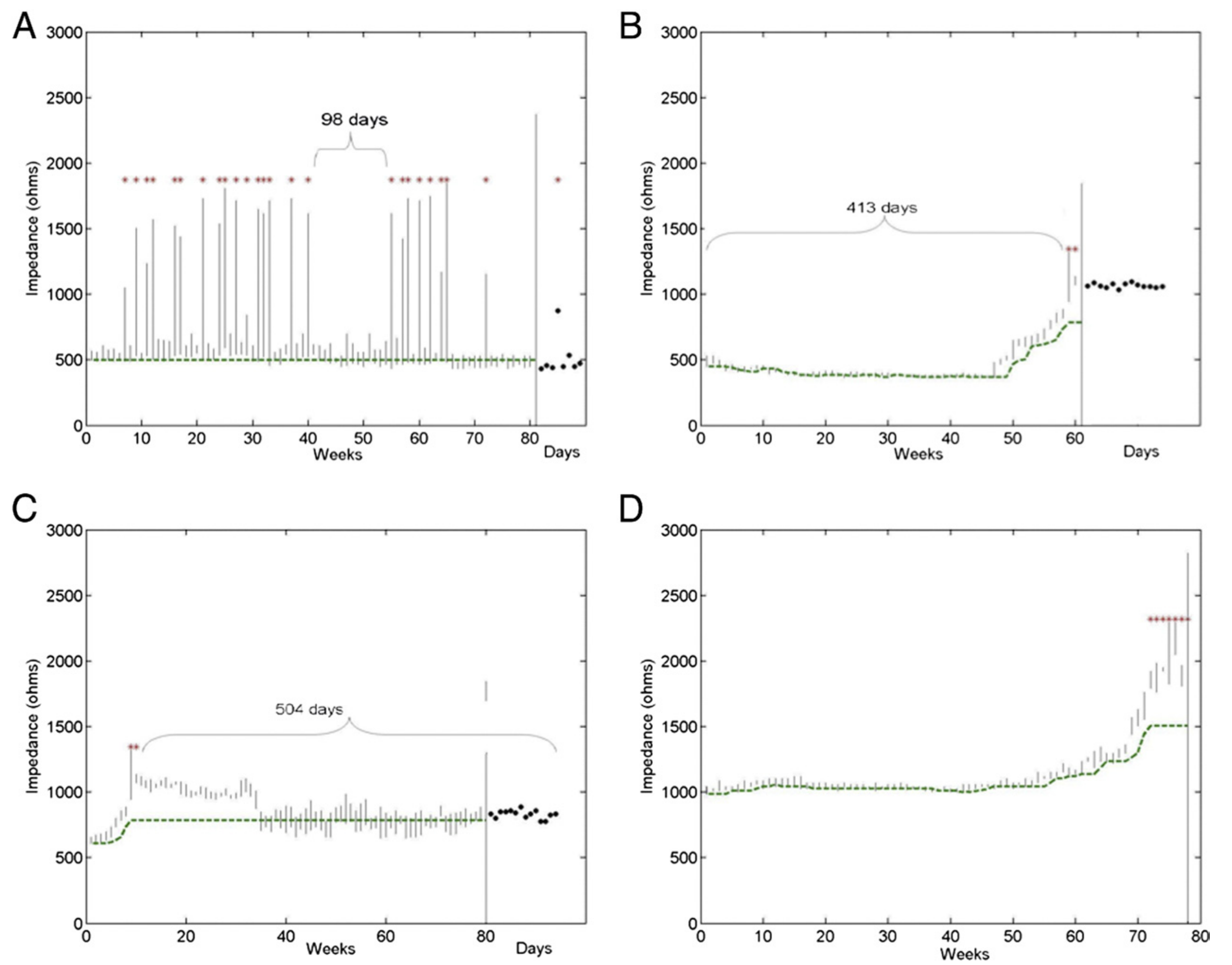

Figure 7 **Impedance Trends for Individual Patients Misclassified by Algorithm**

See text for details and the legend to Figure 3 for explanation of symbols and abscissa. **(A)** Functioning lead classified as connection problem. **(B)** Functioning lead misclassified as fracture. **(C)** Subsequent data file from same lead as **B,** classifying it as connection problem. **Red stars** denoting abrupt impedance rise correspond to the same time points in **B** and **C.** **(D)** Connection problem misclassified as functioning lead.

three normal leads without impedance rises that were misdiagnosed as fractures because rapid, physiological oversensing was misinterpreted as noise (Fig. 2C) (3,8). These leads were not included in our study.

We found that all impedance rises were abrupt in confirmed fractures or connection problems; stable high impedance occurred in only 1 connection problem, without clinical consequence. In contrast, 43% of functioning leads had either only gradual increases or increases to stable high impedance, suggesting a different mechanism of impedance rise. From a clinical perspective, these leads do not require prompt replacement.

With sufficient follow-up, all functioning leads with abrupt, unstable impedance increases showed impedance trends typical of connection problems. Unfortunately, we do not have radiographs to determine if lead pins were inserted incompletely. All functioning leads also had impedances less than the maximum displayed by the programmer or remote-monitoring (2,500 Ω). This raises the possibility that physicians' decisions to replace functioning leads may be influenced by the range of displayed data.

Study limitations. Because functioning leads remained implanted, we could not analyze them using an RPA reference standard. Thus, we do not know if their impedance increases occurred because of changes at the electrode-myocardial interface, subclinical fractures, or connection problems. We do not know how well our criteria apply to leads or connections from other manufacturers or to other rare types of header or connection problems (9,12–14). We did not analyze criteria for high-voltage fractures. These comprise approximately 10% of Fidelis fractures (17), with or without concomitant pace-sense fractures. The Medtronic RPA database is designed for analyzing returned leads, not for determining the reasons leads were extracted; thus, we do not know what fraction of extracted leads are misdiagnosed as fractures. Algorithm performance may differ when it is applied to implanted leads rather than explanted leads.

Clinical implications. Outside the perioperative period, noise oversensing with normal impedance trend indicates a fracture rather than a connection problem. If noise oversensing and abrupt impedance rise occur, our algorithm assists in differentiating fractures from connection problems. A connection problem may be diagnosed by radiography (10), but the orientation of the pulse generator relative to the x-ray beam may preclude definitive diagnosis. Intraoperatively, the ICD should be inspected for incomplete insertion of the lead pin into the header, loose set screws, and other header problems (14) before disconnecting the lead.

This study provides limited data supporting follow-up without operative intervention for leads with a gradual impedance rise. For leads with an abrupt rise and no other evidence of ICD system malfunction, operative intervention is indicated if the algorithm indicates a fracture; however, we cannot provide an evidence-based recommendation if the algorithm indicates a connection problem. About one-half of high-impedance, functioning leads had impedance trends indistinguishable from connection problems with a maximum impedance $<$2,500 Ω.

Finally, this study highlights uncertainties in clinical diagnosis that may influence reported rates of lead fractures. Studies of lead fractures should indicate the specific criteria used for diagnosis.

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Key Words: defibrillators ■ implantable cardioverter-defibrillator lead fracture ■ lead failure.

APPENDIX

For data for individual leads in the development set, please see the online version of this paper.